

### **Remarks/Arguments**

Claims 1-10, 12, 24 and 27-33 are pending in the application. Claims 3-5, 7, 8, 10, 16, 19, 20, 23, 24, 29 and 33 have been withdrawn from consideration. Applicants reserve the right to pursue inventive subject matter no longer or not yet claimed in this or a related application.

Applicants have carefully reviewed all of the rejections and objections set forth in the Office Action and respond fully below. Applicants thus respectfully request reconsideration in view of the following remarks.

#### Conditional Request for Telephonic Interview

Applicants request a telephonic interview prior to any subsequent action, should the claims not initially be found in allowance subsequent to this response. The undersigned may be reached at (858) 228-7829.

#### Drawings

The specification as originally filed contained color drawings. The Office Action requested a petition accompanied by the appropriate fee, three sets of color drawings or color photographs and an amendment to include language as the first paragraph of the brief description of the drawings section of the specification be submitted.

Applicants had previously submitted such a Petition, appropriate fees and three sets of color drawings to the U.S. Patent Office on February 13, 2004 with the filing of the application. The specification as filed also contains the required language regarding color drawings as the first paragraph of the brief description (page 3, lines 2-4).

Applicants' Petition was granted on August 9, 2006.

Copies of Applicants' previously filed Petition for Filing Color Drawings and the Office Communication issued August 9, 2006 granting that Petition are attached hereto as Exhibit A for the Examiner's convenience.

Withdrawal of the objection to the drawings is respectfully requested.

Information Disclosure Statement

Applicants had previously filed an Information Disclosure Statement with two series of substitute Forms 1449, one series labeled sheets 1 through 8, and a second series labeled sheets 1 through 11. With the current Office Action, one of these series was returned and initialed by the Examiner. Return of the second series of initialed substitute 1449s, receipt of which by the PTO has been confirmed by postcard, is respectfully requested.

Election/Restriction

In the recent Office Action, the prior restrictions were maintained. The Office Action asserted that amplification can produce only DNA. This is not correct. As is known to those of skill in the art, RNA may also be amplified. A published article demonstrating amplification of RNA was provided in response to the previous Office Action. Its consideration, and of claim 24, is requested. RNA can be amplified, as known in the art, publication of which was presented.

Further, claim 33 was deemed withdrawn on the basis that the element “polycationic multichromophore” had previously not been presented. This is remarkable, considering that this exact language is found in claim 1, which is under consideration.

Applicants are entitled to present generic claims. The Office Action has confused fluorescein (page 4, numbered paragraph 8), which is presented as a species of elected signaling chromophore, with the polycationic multichromophore genus.

The species elected in response to requirement for election for the “polycationic multichromophore” genus was “conjugated polymer.”

Claim 33 is properly presented as a generic claim covering the elected species, and its consideration is proper. Reconsideration of its withdrawal is respectfully requested. Claim 33 should be examined to the extent which it does read on the elected species, until allowable.

Claim Objections

Claims 1, 2, 6, 12-14, 17, 27, 28 and 32 were objected to for encompassing non-elected embodiments. This objection is traversed.

No legal grounds were stated for this objection. Applicant is entitled to present claims encompassing all embodiments of their invention. All species presented are subject to

examination upon allowance of generic linking claims, which are under consideration here. Applicants elect to maintain the claims presented.

Objection to the Specification

The specification was noted to contain numerous trademarks. Applicants have by amendment above inserted the appropriate trademark symbols, each of which is accompanied by the appropriate generic language.

The rejection under 35 U.S.C. § 112, second paragraph

Claims 1, 2, 6, 9, 12-15, 17-18, 21, 22, 27, 28 and 30-32 were rejected under 35 U.S.C. 112, second paragraph, as allegedly indefinite. This rejection is traversed.

The Office Action asserted that the term “polynucleotide-binding protein” was indefinite. The Office Action identified the definition provided in the specification at page 23, lines 15-20, but alleged that the “definition is non-limiting.”

This is not a legal ground of rejection.

As this term contains only three words, each of which is known in the art, the term is clear and definite to the person of skill. The Office Action did not state which of these three words it found confusing, or whether perhaps the combination was not understood.

For convenience, the legal requirements for establishing an indefiniteness rejection are provided:

"The requirement to 'distinctly' claim means that the claim must have a meaning discernible to one of ordinary skill in the art when construed according to correct principles. Only when a claim remains insolubly ambiguous without a discernible meaning after all reasonable attempts at construction must a court declare it indefinite." *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1366, 71 USPQ2d 1081, 1089 (Fed. Cir. 2004).

The Federal Circuit has explained that a claim will not be invalidated for indefiniteness without a severe defect:

[W]e have not held that a claim is indefinite merely because it poses a difficult issue of claim construction. We engage in claim construction every day, and cases frequently present close questions . . . . We have not insisted that claims be plain on their face in order to avoid condemnation for indefiniteness; rather, what we have asked is that the

claims be amenable to construction, however difficult that task may be. If a claim is insolubly ambiguous, and no narrowing construction can properly be adopted, we have held the claim indefinite. If the meaning of the claim is discernible, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree, we have held the claim sufficiently clear to avoid invalidity on indefiniteness grounds.

*Exxon Research and Eng'g Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001) (emphasis added, internal citations omitted).

MPEP 2173.02 reiterates this, stating that a claim term is definite if its meaning is discernible (citing *Bancorp Services, L.L.C. v. Hartford Life Ins. Co.*, 359 F.3d 1367, 1372, 69 USPQ2d 1996, 1999-2000 (Fed. Cir. 2004)). Only if a claim term is insolubly ambiguous after all reasonable efforts at construction can it be declared indefinite.

No effort at all has been made to construe the term “polynucleotide-binding protein.” The terms “polynucleotide,” “binding” and “protein” are all known in the art, as are proteins that bind to polynucleotides, a number of examples of which are given in the application. Additional discussion of the “polynucleotide-binding protein” can be found in the application at page 22, line 20 through page 24, line 12, and multiple working examples are provided. The person of skill has no difficulty in determining what this phrase means, or what a protein that binds to a polynucleotide is.

As the claim language permits one of skill to determine the metes and bounds of protection, the claims meet the requirements of 35 USC 112, second paragraph. Withdrawal of the rejection is respectfully requested.

The enablement rejection under 35 U.S.C. § 112, first paragraph

Claims 1, 2, 6, 9, 12-15, 17, 22, 27, 28 and 30-32 were rejected under 35 U.S.C. 112, first paragraph, as allegedly lacking enablement. This rejection is traversed.

Applicants' prior arguments are hereby incorporated by reference and reiterated.

New inappropriate grounds of rejection were stated. One ground improperly focuses on the possibility that any RNA molecule could be detected. This is not a claim element. The

claimed method utilizes a polynucleotide binding protein interacting with a polynucleotide to which it can bind.

The Office Action further states (page 8) that “the specification does not set forth reproducible conditions under which the elected fluorescent dye [which was in fact fluorescein] is produced and used in combination with the elected species of nucleic acid-single stranded RNA.

The Office Action additionally asserts that the specification does not set forth “reproducible conditions under which the polynucleotide binding protein is synthesized and used,” despite the fact that the sequence of the protein exemplified is taught (and known in the art), and was obtained commercially. The examiner is referred to page 24 of the application:

The Tat peptide used in the working examples is easily synthesized by the solid phase method and can be purified by HPLC and characterized by MALDI-TOF mass spectrum and amino acid analysis. The chemical methods for attaching the signaling chromophore to the peptide to form the signaling sensor PBP-C\* are known.[citing G. T. Hermanson, *Bioconjugate Techniques*, Academic Press, San Diego, 1996] **A specific example is the signaling Tat-C\* with fluorescein at the N-terminus.** Specific PBP-C\* structures can be made to order by commercial sources.

(emphasis added). Not only do those of skill in the art understand how to N-label peptides with fluorescein, a publication for doing so was cited in the specification.

No evidence has been provided that the conditions and materials set forth in the application are not reproducible. If the examiner is relying on personal knowledge, he is requested to provide this information in affidavit form, as is required, so that it may be rebutted.

The working examples provide specific techniques for detecting a viral component of a virus currently plaguing humankind. Detection of that viral component in a sample is of immediate apparent utility to those of skill in the art, as well as to the general public. The assertions to the contrary in the Office Action are without merit.

Finally, at page 12, paragraph 28, the Office Action states that “it is not a requirement that al[l] of the [Wands] factors be addressed” in an enablement rejection. The Federal Circuit and Board of Patent Appeals and Interferences would be interested to learn of this. The Patent and Trademark Office’s own training materials state:

It is improper to conclude that a disclosure is not enabling based on an analysis of only one of the above factors while ignoring one or more of the others. The examiner's analysis must consider all the evidence related to each of these factors, and any conclusion of non-enablement must be based on the evidence as a whole. *Id.* at 737 & 740, 8 USPQ2d at 1404 & 1407.

Training Materials at III, emphasis added. All *Wands* factors must be analyzed, particularly where, as here, the ignored factors strongly favor the Applicants.

For the grounds previously stated, as well as the arguments above, the strained enablement rejection is without merit. Withdrawal is requested and appropriate.

The rejection under 35 U.S.C. §101

Claims 1, 2, 6, 9, 12-15, 17, 22, 27, 28 and 30-32 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility. This rejection is traversed.

The only ground for this rejection was stated to be:

“The method is not required to have any level of specificity, or that the target single-stranded RNA has any specific, substantial, and credible utility.”

Office Action, page 15, paragraph number 37. The meaning of this is not discernible, and does not clearly set forth a ground of rejection, as is required to support a rejection.

As explained at MPEP 2107.01:

Some confusion can result when one attempts to label certain types of inventions as not being capable of having a specific and substantial utility based on the setting in which the invention is to be used. One example is inventions to be used in a research or laboratory setting. Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have a clear, specific and unquestionable utility (e.g., they are useful in analyzing compounds).

A method of detecting and/or quantitating nucleic acids is useful in analyzing compounds (i.e., nucleic acids). Thus, the invention as claimed has a clear, specific and unquestionable utility.

Furthermore, this utility is immediately obvious to one of skill in the art. This is exemplified by the existing commercial market for materials and methods useful in detecting and quantitating nucleic acids, as is known to those of skill in biotechnology. See exhibits B from

Sigma/Aldrich, Pierce and Invitrogen, demonstrating their marketed technologies for nucleic acid detection and quantitation.

Withdrawal of the rejection is respectfully requested.

The “how to use” rejection under 35 U.S.C. § 112, first paragraph

Claims 1, 2, 6, 9, 12-15, 17, 22, 27, 28 and 30-32 were rejected under 35 U.S.C. 112, first paragraph, on the ground that one of skill would allegedly not know how to use the invention.

This rejection is traversed.

MPEP 2164.01(c) states:

If a statement of utility in the specification contains within it a connotation of how to use, and/or the art recognizes that standard modes of administration are known and contemplated, **35 U.S.C. 112** is satisfied. *In re Johnson*, 282 F.2d 370, 373, 127 USPQ 216, 219 (CCPA 1960); *In re Hitchings*, 342 F.2d 80, 87, 144 USPQ 637, 643 (CCPA 1965). See also *In re Brana*, 51 F.2d 1560, 1566, 34 USPQ2d 1437, 1441 (Fed. Cir. 1993).

Applicants have included a statement of utility in their specification, and have additionally provided working examples of their invention. Multiple examples of detection of polynucleotides are provided, as acknowledged in the Office Action (page 7, last paragraph).

As stated above, contrary to the assertion in the Office Actions, the working examples clearly describe binding **to RNA** polynucleotides. See example 4, page 30:

The Tat-C\* probe ([Tat-C\*] =  $1.0 \times 10^{-8}$  M) was mixed with an equimolar amount of the TAR **RNA** at room temperature, and in an identical fashion with a non-specific dTAR **RNA**.

(emphasis added). Examples 5, 6 and 7 additionally provide working embodiments of binding of a protein to an RNA polynucleotide.

Consequently, the asserted ground of rejection is without support. Withdrawal is respectfully requested.

Exhibits

Exhibits A and B are filed herewith and hereby incorporated by reference.

**CONCLUSION**

Applicants respectfully submit that the claims are in condition for allowance. As such, they respectfully request the Office to promptly issue a notice of allowance following the submission of such further documentation. Of course, if any issue remains that can be dealt with absent a formal action and response thereto, the Examiner is encouraged to telephone the undersigned at his earliest convenience so that the same may be expeditiously resolved.

Respectfully submitted,

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